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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,846	09/17/2001	Y. Tom Tang	PF-0556-1 DIV	9384

22428 7590 12/03/2004

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER
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LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/954,846	<b>Applicant(s)</b> TANG ET AL.	
	<b>Examiner</b> Ruixiang Li	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3-7,9,11-17,27,28 and 46 is/are pending in the application.
- 4a) Of the above claim(s) 13-17,27, and 28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-7, 9, 11, and 46 is/are allowed.
- 6) ☒ Claim(s) 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **Status of Application**

The Request filed on 08/04/2004 for Continued Examination (RCE) under 37 CFR 1.114 of Application 09/954,846 is granted. An action on the RCE follows.

### **Applicants' Amendment and Claims**

Applicants' amendment on 08/04/2004 has been entered in full. Claims 3, 4, 9, 11, and 12 have been amended. Claims 3-7, 9, 11-17, 27, 28, and 46 are pending. Claims 3-7, 9, 11, 12, and 46 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **Withdrawn Objections and/or Rejections**

The rejections of claims 3, 6, 7, 9, 11, and 12 under 35 USC § 112, 1<sup>st</sup> paragraph (Scope of Enablement and Written Description), as set forth at pages 3-5 of the office action (Paper No. 8, September 24, 2003), have been withdrawn in view of Applicants' amendment to the claims.

**Claim Rejection under 35 USC § 112, 1<sup>st</sup> paragraph (Scope of Enablement)**

The rejection of claim 12 under 35 USC § 112, 1<sup>st</sup> paragraph (Scope of Enablement), as set forth at pages 5-7 of the office action (Paper No. 8, September 24, 2003), is maintained.

It is noted that claim 12 has been amended to recite an intended use, "for detecting the complete complement of the polynucleotide of claim 11". However, recitation of such an intended use does not limit the scope of the claimed invention and the scope of enablement rejection remains for the following reasons.

Claim 12 recites an isolated polynucleotide comprising at least 60 contiguous nucleotides of SEQ ID NO: 4 or a polynucleotide of claim 11 (homologues of SEQ ID NO: 4). However, other than the polynucleotide sequence of SEQ ID NO: 4 encoding the polypeptide of SEQ ID NO: 2, the specification fails to provide sufficient guidance, information or working examples regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claim. The disclosure does not show (i) which portions of SEQ ID NO: 4 are critical to the activity of the proteins encoded by the nucleic acids; and (ii) what modifications (e.g., substitutions, deletions or additions) one can make to SEQ ID NO: 4 will result in protein mutants with the same functions as the protein of SEQ ID NO: 2. The state of the art (See, e.g., Ngo, et al, *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz, et al.

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(ed.), Birkhauser, Boston, MA, pp. 433 and 492-495) is such that the relationship between sequence of a protein and its activity is not well understood and is not predictable. Excising out portions of a protein or modifications to a protein, e.g., by substitutions or deletions, would often result in deleterious effects to the overall activity and effectiveness of the protein.

Accordingly, the disclosure fails to enable such a myriad of the claimed nucleic acid molecules that not only vary substantially in length but also in nucleic acid composition and to provide any guidance to one skilled in the art on how to make and use the claimed genus of nucleic acid molecules. Thus, it would require undue experimentation for one skilled in the art to make and use the claimed genus of the molecules embraced by the instant claim.

**Claim Rejections under 35 USC § 112, 1<sup>st</sup> paragraph (Written Description)**

The rejection of claim 12 under 35 USC § 112, 1<sup>st</sup> paragraph (Written Description), as set forth at pages 7-9 of the office action (Paper No. 8, September 24, 2003), is maintained.

Claim 12 is are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The description discloses a polynucleotide of SEQ ID NO: 4 that encodes a polypeptide of SEQ ID NO: 2. However, claim 12, as written, recites an isolated polynucleotide comprising at least 60 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO: 4 or a polynucleotide of claim 11 (homologues of SEQ ID NO: 4). Thus, the claim encompasses a huge number of nucleic acids that vary substantially both in length and in nucleotide composition. In fact, the claims encompass virtually any random nucleic acid sequence of any length as long as it comprises at least 60 nucleotides of SEQ ID NO: 4 or its homologues.

The instant disclosure of a single species of nucleic acid of SEQ ID NO: 4 that encodes the polypeptide of SEQ ID NO: 5 does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant disclosure fails to provide sufficient description information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions that are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be

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tolerated and there is no information regarding the relation of structure to function. Furthermore, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed polynucleotides as being identical to those instantly claimed.

Due to the breadth of the claim genus and lack of the definitive structural or functional features of the claimed genus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus.

### **Suggestion**

The following claim language is suggested to overcome the rejections under 35 USC § 112, 1<sup>st</sup> paragraph:

An isolated polynucleotide consisting of at least 60 contiguous nucleotides of the nucleic acid sequence of SEQ ID NO: 4 or a complement thereof, wherein said polynucleotide hybridizes under highly stringent conditions to the nucleic acid sequence of SEQ ID NO: 4 or a complement thereof, wherein said highly stringent conditions are X, Y, and Z.


### **Conclusion**

No claims are allowed.

**Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.



Ruixiang Li, Ph.D.  
Examiner  
December 2, 2004